

Ramon Rossi Lopez - rlopez@lopezmchugh.com
(California Bar Number 86361; admitted *pro hac vice*)
Lopez McHugh LLP
100 Bayview Circle, Suite 5600
Newport Beach, California 92660
949-812-5771

Mark S. O'Connor (011029) – mark.oconnor@gknet.com
Gallagher & Kennedy, P.A.
2575 East Camelback Road
Phoenix, Arizona 85016-9225
602-530-8000

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products
Liability Litigation

No. MD-15-02641-PHX-DGC

Case No. 2:16-cv-00853-DGC

DEBRA MULKEY, an individual,
Plaintiff,

v.

C.R. BARD, INC., a New Jersey
corporation and BARD PERIPHERAL
VASCULAR, an Arizona corporation,
Defendants.

**PLAINTIFF'S CONTROVERTING
STATEMENT OF FACTS IN OPPOSITON
TO BARD'S MOTION FOR SUMMARY
JUDGMENT AS TO PLAINTIFF DEBRA
MULKEY'S CLAIMS**

1. Plaintiff Debra Mulkey received a Bard Eclipse® Filter (the "Filter") on April 11, 2012, before she underwent bariatric surgery. (Ex. A, Plaintiff Fact Sheet of Plaintiff Debra Mulkey (hereinafter "PFS"), at §§ II.2(a), II.3).

RESPONSE: Uncontroverted.

2. The Filter is not sold directly to patients. (Ex. B, Eclipse Filter Instructions for Use (the "Eclipse IFU") at page 1).

RESPONSE: Controverted. Defendants fail to properly support their assertion of fact as required by Rule 56(c). The Eclipse IFU cited by Defendants states, "Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician." The Eclipse IFU does not support Defendants' contention that the Filter is not (or cannot be) sold directly to patients. Further, the Detailed Bill for Debra Mulkey (Ex.

1 A) shows that Debra Mulkey was sold a Bard Vena Cava Filter System
2 directly by the medical provider and was charged \$2,031.25.
3 Defendants' SOF is silent as to the identity of the seller at issue.

4 3. Plaintiff's implanting physician, Dr. Roderick Tompkins, testified that he
5 placed the Filter in Plaintiff [REDACTED]
6 [REDACTED] (Ex. C, April 11, 2017 Dr. Roderick Tompkins Deposition Transcript
7 ("Tompkins Dep. Tr.") at 176:2 to 177:10).

8 **RESPONSE: Controverted. The testimony cited by Defendants**
9 **actually states that Dr. Tompkins** [REDACTED]
10 [REDACTED] **Def. Ex. C at 177:4-7. It is**
11 **unclear what a** [REDACTED] **means as used herein.**

12 4. At the time Plaintiff received her Filter, [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED] (Ex. D, Selected Plaintiff Medical Records).

17 **RESPONSE: Uncontroverted as to the selected wording of the medical**
18 **history from the records, but controverted that this medical history**
19 **constitutes a material fact. There is no evidence in this case that**
20 **anything about Ms. Mulkey's prior medical history caused or**
21 **contributed to cause her filter to caudally migrate, tilt, become**
22 **irretrievable, perforate her vena cava, surrounding organs and spine,**
23 **and/or fracture. To the contrary, the evidence in this case is that the**
24 **defective design of Ms. Mulkey's Eclipse IVC filter caused her injuries**
25 **and complications.**

26 5. Dr. Tompkins testified that before he placed the Filter, he had the IFU that
27 accompanied the Filter available to him to read. (Ex. C, Tompkins Dep. Tr. at 173:6-24.)

28 **RESPONSE: Uncontroverted.**

 6. The Eclipse IFU applicable in April 2010 (when Plaintiff received her
Filter) included the following warnings:

- a. Under the bolded heading "**Potential Complications**," the Eclipse
IFU reads as follows:
 - Movement, migration or tilt of the filter are known
complications of vena cava filters. Migration of filters to
the heart or lungs has been reported. There have also been
reports of caudal migration of the filter.

- Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
- Perforation or other acute or chronic damage of the IVC wall.

* * *

- Filter Tilt

* * *

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

(Ex. B, Eclipse IFU).

- b. Under the bolded “**Eclipse Filter Removal**” heading, the Eclipse IFU states in bolded language as follows:

It is possible that complications such as those described in the “Warnings”, “Precautions,” or “Potential Complications” sections of this Instructions for Use may affect the recoverability of the device and result in the clinician’s decision to have the device remain permanently implanted.

(Ex. B, Eclipse IFU).

RESPONSE: Uncontroverted that the referenced language is included in the applicable Eclipse IFU. Controverted that the cited language addresses or has any bearing on Plaintiff’s causes of action for failure to warn. Plaintiff’s failure to warn claim, among other bases, is that the language contained in the Eclipse IFU failed to convey the increased severity and frequency of the complications with that filter (and all of Bard’s predecessor filters to the Eclipse).

7. Dr. Tompkins testified that he would be speculating as to whether information and alleged facts told to him by Plaintiff’s counsel would have altered his treatment decision for Plaintiff. Specifically, he testified as follows:

1 13 Q And it's important for you to rely on
2 14 accurate or reliable information, isn't that
3 15 right –

4 16 A Yes.

5 17 Q -- in making a decision as a medical
6 18 doctor?

7 19 A Yes.

8 20 Q Okay. So -- so again, being shown a
9 21 draft e-mail and asked if you had known, if you
10 22 had known, would you have made a different
11 23 decision, *you're really speculating, aren't you?*

12 24 MR. DeGREEFF: Object to the form.

13 25 A *Yes*.

14 1 Q Doctor, would you need much more
15 2 information other than an e-mail or a couple of
16 3 documents provided to you with testimony by
17 4 counsel in making a decision whether you would use
18 5 a product or not?

* * *

19 8 A Can you restate that?

20 9 Q Sure.

21 10 Would you need information beyond
22 11 documents taken out of context -- internal
23 12 documents taken out of context to make a decision
24 13 as to whether you would use a product or not?

25 14 MR. DeGREEFF: Object to form. Same
26 15 objection.

27 16 A Yes.

28 (Ex. C, Tompkins Dep. Tr. 184:13 to 185:16).

RESPONSE: Controverted. Defendants accurately cited the “cherry picked” testimony from pages 184:13 to 185:16 of Dr. Tompkins’ deposition. However, Plaintiff controverts Defendants’ summary of Dr. Tompkins’ testimony and that it is consistent with the totality of his deposition testimony. Dr. Tompkins did not testify that he would be speculating as to whether the information and documents he was shown at his deposition would change his treatment decision. To the contrary, Dr. Tompkins testified as follows:

- **“I wouldn’t use the filter if I was aware that deaths were occurring concurrently with me placing these filters.” (Ex. C, Tompkins Dep. Tr. at 53:7-23).**
- **If the Eclipse IFU had informed him of a significant difference in the risk of migration over other filters, he wouldn’t have used the filter. (Ex. C, Tompkins Dep. Tr. at 108:20 to 109:1). But the Eclipse IFU did not inform Dr. Tompkins that the Eclipse had a higher risk of movement, migration or tilt than any other filter. (Ex. C, Tompkins Dep. Tr. at 108:3-9).**
- **If the Eclipse had an increased risk of migration over other filters, that is something he would have wanted to know and something he would have taken into account in his risk benefit analysis on whether to use the filter. (Ex. C, Tompkins Dep. Tr. at 108:10-19).**
- **If the Eclipse had an increased risk of migration over other filters that would affect Dr. Tompkins’ prescribing habits and, if it was a significant difference, he wouldn’t use the filter. (Ex. C, Tompkins Dep. Tr. at 108:20 to 109:1).**
- **If the IFU included pertinent warnings, that is something Dr. Tompkins would pass on to his patients. (Ex. C, Tompkins Dep. Tr. at 106:7-10).**
- **There were risks and problems with Bard’s filters that Bard did not tell Dr. Tompkins about. (Ex. C, Tompkins Dep. Tr. at 216:3-8).**
- **The Eclipse IFU did not inform Dr. Tompkins of an increased risk of movement, migration or tilt with Bard filters versus competitor filters. (Ex. C, Tompkins Dep. Tr. at 107:17-21).**
- **The Eclipse IFU did not inform Dr. Tompkins of an increased risk of movement, migration or tilt with Bard optional filters versus Bard permanent filters. (Ex. C, Tompkins Dep. Tr. at 107:22 to 108:2).**

1 8. Dr. Tompkins never testified that had he been given different information
2 about the Eclipse Filter, it is probable that he would have decided against using the
3 device.

4 **RESPONSE: Controverted. Dr. Tompkins testified:**

- 5 • **“I wouldn’t use the filter if I was aware that deaths were**
6 **occurring concurrently with me placing these filters.” (Ex. C,**
7 **Tompkins Dep. Tr. at 53:7-23).**
- 8 • **If the Eclipse had an increased risk of migration over other**
9 **filters, a significant difference that would affect Dr. Tompkins’**
10 **prescribing habits and he wouldn’t use the filter. (Ex. C,**
11 **Tompkins Dep. Tr. at 108:20 to 109:1).**
- 12 • **If the Eclipse had an increased risk of migration over other**
13 **filters, that is something that Dr. Tompkins would have wanted**
14 **to know. (Ex. C, Tompkins Dep. Tr. at 108:10-15).**
- 15 • **If the Eclipse had an increased risk of migration over other**
16 **filters, that is something that Dr. Tompkins would have taken**
17 **into account in his risk benefit analysis on whether to use the**
18 **filter and it would have affected his prescribing habits. (Ex. C,**
19 **Tompkins Dep. Tr. at 108:16-22).**
- 20 • **He expected Bard to notify him immediately if it was aware of**
21 **problems with the design of one of its filters that was causing**
22 **complications and problems for patients, or if it was in the**
23 **process of redesigning its filter to reduce complications. (Ex. C,**
24 **Tompkins Dep. Tr. at 125:2-14). Dr. Tompkins wanted to know**
25 **this information because it would help him decide whether he**
26 **even wanted to use the filter. (Ex. C, Tompkins Dep. Tr. at**
27 **125:2-18).**
- 28 • **There were risks and problems with Bard’s filters that Bard did**
 not tell Dr. Tompkins about. (Ex. C, Tompkins Dep. Tr. at
 216:3-8).
- **The Eclipse IFU did not inform Dr. Tompkins of an increased**
 risk of movement, migration or tilt with Bard filters versus
 competitor filters. (Ex. C, Tompkins Dep. Tr. at 107:17-21).
- **The Eclipse IFU did not inform Dr. Tompkins of an increased**
 risk of movement, migration or tilt with Bard optional filters
 versus Bard permanent filters. (Ex. C, Tompkins Dep. Tr. at
 107:22 to 108:2).

- **The Eclipse IFU did not inform Dr. Tompkins that the Eclipse had a higher risk of movement, migration or tilt than any other filter. (Ex. C, Tompkins Dep. Tr. at 108:3-9).**

9. Dr. Tompkins testified that he relied on his experience, the experience of his colleagues, and the applicable medical literature when he decided to implant an Eclipse Filter in Ms. Mulkey. (Ex. C, Tompkins Dep. Tr. 202:7-22).

RESPONSE: Uncontroverted with clarification. The items listed by Defendants in this SOF are accurate but do not include the entire basis for Dr. Tompkins' decision to implant the Eclipse filter. For example, prior to his decision to implant the Eclipse Filter in Ms. Mulkey, Dr. Tompkins had seen the IFU for the Bard Eclipse filter, and it is his practice to review the IFU for new devices prior to implanting them in patients. (Ex. C, Tompkins Depo at 105:11-23). Additionally, he had received information from Bard sales representatives who attended the placement of filters in bariatric surgery patients by Dr. Tompkins to provide him information if he had questions. (Ex. C, Tompkins Dep. Tr. at 210:1-13; 105:15-18). This was an issue because there were risks and problems with Bard's filters that it did not tell Dr. Tompkins about. (Ex. C, Tompkins Dep. Tr. at 216:3-8). Dr. Tompkins wanted to use the safest available IVC filter that would establish the goal of stopping pulmonary embolisms. (Ex. C, Tompkins Dep. Tr. at 109:2-6). At the time it was implanted, Dr. Tompkins did not expect the filter to tilt and become irretrievable. (Ex. C, Tompkins Dep. Tr. at 97:25 – 98:3). At the time it was implanted, Dr. Tompkins did not expect the filter to perforate Ms. Mulkey's vena cava or other organs in the future. (Ex. C, Tompkins Dep. Tr. at 98:17-25). If Dr. Tompkins had expected these issues to occur, he would not have used the filter. (Ex. C, Tompkins Dep. Tr. at 99:1-5).

10. Dr. Tompkins testified that he does not rely on information from medical device manufacturers, such as Bard, when deciding which IVC filter he wanted to use. Specifically, Dr. Tompkins testified as follows:

19 Q So -- so in -- in deciding which --
20 which filter to use, do you rely on information
21 from the manufacturer?

22 A No.

(Ex. C, Tompkins Dep. Tr. 88:19-22).

RESPONSE: Controverted. Plaintiff does not controvert that the testimony from pages 88:19-22 is cited accurately. However, other testimony from Dr. Tompkins proves this to be untrue. For example, prior to his decision to implant the Eclipse Filter in Ms. Mulkey, Dr. Tompkins had seen the IFU for the Bard Eclipse filter, and it is his practice to review the IFU for new devices prior to implanting them in patients. (Ex. C, Tompkins Depo at 105:11-23). Additionally, he had received information from Bard sales representatives who attended the placement of filters in bariatric surgery patients by Dr. Tompkins to provide him information if he had questions. (Ex. C, Tompkins Dep. Tr. at 210:1-13; 105:15-18). This was an issue because there were risks and problems with Bard's filters that it did not tell Dr. Tompkins about. (Ex. C, Tompkins Dep. Tr. at 216:3-8). Dr. Tompkins further testified that he expected Bard to notify him immediately if it was aware of problems with the design of one of its filters that was causing complications and problems for patients, or if it was in the process of redesigning its filter to reduce complications. (Ex. C, Tompkins Dep. Tr. at 125:2-14). Dr. Tompkins wanted to know this information because it would help him decide whether he even wanted to use the filter. (Ex. C, Tompkins Dep. Tr. at 125:2-18). Dr. Tompkins also would have expected Bard to inform him of problems with filters such as the Eclipse, and to provide him with accurate and thorough information as it became aware of problems with its filters. (Ex. C, Tompkins Dep. Tr. at 57:6-11; 157:22-25). All of this was because Dr. Tompkins wanted to use the safest available IVC filter that would establish the goal of stopping pulmonary embolisms. (Ex. C, Tompkins Dep. Tr. at 109:2-6).

11. Dr. Tompkins testified he does not recall discussions with Bard's sales representatives regarding the use of IVC filters in bariatric patients. (Ex. C, Tompkins Dep. Tr. 55:10-13).

RESPONSE: Controverted. Plaintiff does not controvert that the deposition testimony is cited accurately. However, this testimony is in dispute given other excerpts from Dr. Tompkins' deposition. For example, Dr. Tompkins testified that Bard sales representatives were present when he was performing IVC placements in bariatric patients to provide him information if needed. ((Ex. C, Tompkins Dep. Tr. at 55:5-9; 210:1-13). Dr. Tompkins further testified that he does not remember ever being told by any Bard sales representative that IVC filters should not be used in bariatric patients. (Ex. C, Tompkins Dep. Tr. at 55:14-17).

12. Dr. Tompkins testified that he discussed with Ms. Mulkey the risks and benefits of IVC filter placement, and then obtained her informed consent before placing the Filter. (Ex. C, Tompkins Dep. Tr. at 80:22 to 81:5; 86:3-11; 94:2-15).

RESPONSE: Controverted. Dr. Tompkins testified that he did not consent Ms. Mulkey to complications and injuries caused by failure of the Eclipse filter; instead, he consented her only to certain risks associated with the implant surgery itself. (Ex. C, Tompkins Dep. Tr. at 80:22 – 86:2; 94:21 – 95:25). He further testified that he did not inform Ms. Mulkey:

- About the risk of her IVC filter perforating the vena cava at any time after surgical insertion. (Ex. C, Tompkins Dep. Tr. at 82:3-8; 84:5-10).
- That the IVC filter could in the future penetrate the inferior vena cava and potentially surrounding organs. (Ex. C, Tompkins Dep. Tr. at 84:11-15).
- Of the potential for the filter to migrate caudally following surgical insertion. (Ex. C, Tompkins Dep. Tr. at 84:17-23).
- Of the potential for the filter to migrate cranially after placement. (Ex. C, Tompkins Dep. Tr. at 84:24 to 85:3).
- About the risk of dislodgment of the filter at any time after surgical insertion. (Ex. C, Tompkins Dep. Tr. at 82:9-25).
- About the potential irretrievability of the filter. (Ex. C, Tompkins Dep. Tr. at 83: 3-5).
- About the potential that the IVC filter may perforate the vena cava in the future. (Ex. C, Tompkins Dep. Tr. at 83:6-19).

Ms. Mulkey confirmed in her deposition that [REDACTED] (Ex. D, Mulkey Dep. Tr. at 183:13-16). She did not believe that s [REDACTED]. (Ex. D, Mulkey Dep. Tr. at 182:4-8). For example:

- Ms. Mulkey did not believe [REDACTED] (Ex. D, Mulkey Dep. Tr. at 182:9-13).

- 1 • Ms. Mulkey did not [REDACTED]
2 [REDACTED]. (Ex. D, Mulkey Dep. Tr. at 182:14-16; Ex. C,
3 Tompkins Dep. Tr. at 83:20 to 84:4).
- 4 • Ms. Mulkey did not [REDACTED]. (Ex. D,
5 Mulkey Dep. Tr. at 182:18-20).
- 6 • Ms. Mulkey did not [REDACTED]
7 [REDACTED]. (Ex. D, Mulkey Dep. Tr. at 182:21-24).
- 8 • Ms. Mulkey did not [REDACTED]
9 [REDACTED]. (Ex. D, Mulkey Dep. Tr. at 182:25 to 183:3).
- 10 • Ms. Mulkey did not [REDACTED]
11 [REDACTED]. (Ex. D, Mulkey Dep. Tr. at 183:4-7).
- 12 • Ms. Mulkey did not [REDACTED] (Ex. D,
13 Mulkey Dep. Tr. at 183:8-10).

14 13. On May 21, 2012, Plaintiff [REDACTED]
15 [REDACTED] (Ex. D, Selected Plaintiff Medical Records).

16 **RESPONSE: Uncontroverted.**

17 14. On October 4, 2012, Ms. Mulkey underwent an unsuccessful percutaneous
18 Filter removal procedure with Dr. Pho Nguyen. (Ex. D, Selected Plaintiff Medical
19 Records).

20 **RESPONSE: Uncontroverted.**

21 15. The operative note from Plaintiff's October 4, 2012, unsuccessful removal
22 procedure states that "[t]here is [] tilting of the IVC filter with the tip abutting the medial
23 wall of the IVC," and the doctor was "unable to capture of the IVC filter due to the
24 angulation of the IVC filter." (Ex. D, Selected Plaintiff Medical Records).

25 **RESPONSE: Uncontroverted.**

26 16. Plaintiff testified that on October 4, 2012, she understood Dr. Nguyen "was
27 having some problems" trying to remove the Filter, that the Filter "had grown into the
28 vein," that further attempts to remove the Filter could "caus[e] too much damage to my
vein," and that, as a result, Dr. Nguyen would be unable to retrieve her Filter. (Ex. E,

February 8, 2017 Debra Mulkey Deposition Transcript (“Mulkey Dep. Tr.”) at 95:17 to 97:1).

RESPONSE: Controverted. Plaintiff does not controvert that the testimony is accurately cited. Plaintiff controverts that this testimony accurately summarizes Ms. Mulkey’s entire understanding at that time. Ms. Mulkey testified:

- She was not [REDACTED]. (Ex. D, Mulkey Dep. Tr. at 98:4-6).
- Dr. Nguyen did not [REDACTED]. (Ex. D, Mulkey Dep. Tr. at 180:11-13).
- She was not [REDACTED]. (Ex. D, Mulkey Dep. Tr. at 113:12-20).
In fact, [REDACTED] (Ex. D, Mulkey Dep. Tr. at 137:14-25). Dr. Tompkins confirmed he did not ever tell Ms. Mulkey that her IVC filter was defective, that Bard had injured her or caused her harm, or that her IVC filter was unsafe. (Ex. C, Tompkins Dep. Tr. at 115:19-116:3).
- At the time of her failed IVC removal in October of 2012, she:
 - did not [REDACTED]. (Ex. D, Mulkey Dep. Tr. at 179:21 – 180:1).
 - did not [REDACTED]. (Ex. D, Mulkey Dep. Tr. at 180:2-5).
 - did not [REDACTED]. (Ex. D, Mulkey Dep. Tr. at 180:5-10).

Ms. Mulkey testified [REDACTED].

(Ex. D, Mulkey Dep. Tr. at 185:3-14).

17. Plaintiff testified that on October 4, 2012, she understood there was “some reason” why Dr. Nguyen was unable to remove her Filter. (Ex. E, Mulkey Dep. Tr. at 99:7-10).

RESPONSE: Controverted. Plaintiff does not controvert that the testimony is accurately cited. Plaintiff controverts that this testimony

accurately summarizes Ms. Mulkey's entire understanding at that time. Ms. Mulkey testified:

- She was not [REDACTED] (Ex. D, Mulkey Dep. Tr. at 98:4-6).
- Dr. Nguyen [REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:11-13).
- She was not [REDACTED] (Ex. D, Mulkey Dep. Tr. at 113:12-20). In fact, Dr. Thompson [REDACTED] (Ex. D, Mulkey Dep. Tr. at 137:14-25). Dr. Thompson confirmed he did not ever tell Ms. Mulkey that her IVC filter was defective, that Bard had injured her or caused her harm, or that her IVC filter was unsafe. (Ex. C, Thompson Dep. Tr. at 115:19-116:3).
- At the time of her failed IVC removal in October of 2012, she:
 - did not [REDACTED]. (Ex. D, Mulkey Dep. Tr. at 179:21 – 180:1).
 - did not [REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:2-5).
 - did not [REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:5-10).

Ms. Mulkey testified [REDACTED]

(Ex. D, Mulkey Dep. Tr. at 185:3-14).

18. Plaintiff testified that on October 4, 2012, she knew she no longer needed her Filter. (Ex. E, Mulkey Dep. Tr. at 97:13-17).

RESPONSE: Controverted. Plaintiff does not controvert that the testimony is accurately cited. Plaintiff controverts that this testimony accurately summarizes Ms. Mulkey's entire understanding at that time. Ms. Mulkey testified:

- She was not [REDACTED] e. (Ex. D, Mulkey Dep. Tr. at 98:4-6).

- **Dr. Nguyen** [REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:11-13).
- **She was not** [REDACTED] (Ex. D, Mulkey Dep. Tr. at 113:12-20).
In fact, **Dr. Thompson** [REDACTED] (Ex. D, Mulkey Dep. Tr. at 137:14-25). Dr. Thompson confirmed he did not ever tell Ms. Mulkey that her IVC filter was defective, that Bard had injured her or caused her harm, or that her IVC filter was unsafe. (Ex. C, Thompson Dep. Tr. at 115:19-116:3).
- **At the time of her failed IVC removal in October of 2012, she:**
 - **did not** [REDACTED] (Ex. D, Mulkey Dep. Tr. at 179:21 – 180:1).
 - **did not** [REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:2-5).
 - **did not** [REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:5-10).

Ms. Mulkey testified [REDACTED]
[REDACTED]
(Ex. D, Mulkey Dep. Tr. at 185:3-14).

19. Plaintiff testified that on October 4, 2012, she was “upset” that her filter could not be removed. (Ex. E, Mulkey Dep. Tr. at 185:3-9 (“[I]t upset me when I found out it [the Filter] couldn’t be removed.”)).

RESPONSE: Controverted. Plaintiff does not controvert that the testimony is accurately cited. Plaintiff controverts that this testimony accurately summarizes Ms. Mulkey’s entire understanding at that time. Ms. Mulkey testified:

- **She was not** [REDACTED] (Ex. D, Mulkey Dep. Tr. at 98:4-6).
- **Dr. Nguyen** [REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:11-13).
- **She was not** [REDACTED] (Ex. D, Mulkey Dep. Tr. at 113:12-20).

In fact, Dr. Tompkins [REDACTED] (Ex. D, Mulkey Dep. Tr. at 137:14-25). Dr. Tompkins confirmed he did not ever tell Ms. Mulkey that her IVC filter was defective, that Bard had injured her or caused her harm, or that her IVC filter was unsafe. (Ex. C, Tompkins Dep. Tr. at 115:19-116:3).

- At the time of her failed IVC removal in October of 2012, she:
 - did not be [REDACTED] (Ex. D, Mulkey Dep. Tr. at 179:21 – 180:1).
 - did not [REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:2-5).
 - did not [REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:5-10).

Ms. Mulkey testified [REDACTED] (Ex. D, Mulkey Dep. Tr. at 185:3-14).

20. Plaintiff testified that the first time she experienced symptoms of any bodily injuries related to her Filter was on October 4, 2012, the day of her unsuccessful removal procedure. (Ex. E, Mulkey Dep. Tr. at 142:8-24).

RESPONSE: Controverted. Plaintiff does not controvert that the testimony is accurately cited. Plaintiff controverts that this testimony accurately summarizes her entire understanding at that time. Ms. Mulkey did not realize at the time it was an injury or that anything was wrong with her filter. (Ex. D, Mulkey Dep. Tr. at 142:8-17 and 143: 14-22; Ex. E Plaintiff Fact Sheet of Plaintiff Debra Mulkey (hereinafter “PFS”), at Section II.13(b) on page 14). To the contrary, Ms. Mulkey testified:

- She was not [REDACTED] (Ex. D, Mulkey Dep. Tr. at 98:4-6).
 - Dr. Nguyen [REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:11-13).
 - She was not [REDACTED] (Ex. D, Mulkey Dep. Tr. at 113:12-20).
- In fact, Dr. Thompson [REDACTED]

1 [REDACTED] (Ex. D,
 2 Mulkey Dep. Tr. at 137:14-25). Dr. Tompkins confirmed he did
 3 not ever tell Ms. Mulkey that her IVC filter was defective, that
 4 Bard had injured her or caused her harm, or that her IVC filter
 was unsafe. (Ex. C, Tompkins Dep. Tr. at 115:19-116:3).

- 5 • At the time of her failed IVC removal in October of 2012, she:
 - 6 ○ did not [REDACTED]. (Ex. D, Mulkey Dep.
 Tr. at 179:21 – 180:1).
 - 7 ○ did not [REDACTED]
 8 [REDACTED] (Ex. D, Mulkey Dep. Tr. at 180:2-5).
 - 9 ○ did not [REDACTED]
 10 [REDACTED] (Ex. D, Mulkey
 Dep. Tr. at 180:5-10).

11 Ms. Mulkey testified [REDACTED]
 12 [REDACTED]
 13 [REDACTED].
 (Ex. D, Mulkey Dep. Tr. at 185:3-14).

14 21. Plaintiff claims that “[i]n October 2015, I saw a commercial on TV that
 15 indicated that IVC filters were causing bodily injuries to people.” (Ex. A, PFS at §
 16 II.13(c)).

17 **RESPONSE: Uncontroverted.**

18 22. Plaintiff testified that she never talked to any of her doctors about her IVC
 19 filter until December 2016. (Ex. E, Mulkey Dep. Tr. at 103:12 to 104:6).

20 **RESPONSE: Uncontroverted.**

21 23. Plaintiff’s vascular and interventional radiologist expert, Dr. Darren Hurst,
 22 testified that Ms. Mulkey’s Filter could be removed via a complex percutaneous
 23 procedure. (Ex. F, July 21, 2017 Dr. Darren Hurst Deposition Transcript (“Hurst Dep.
 24 11 Tr.”) at 100:20 to 101:14).

25 **RESPONSE: Objection, misstates the cited testimony. Controverted.**
 26 In the testimony cited by Defendants, Dr. Hurst actually testified that
 27 Ms. Mulkey’s filter could “potentially be removed percutaneously via a
 28 complex procedure.” (Ex. F, “Hurst Dep. Tr.” at 100:20-23). He

1 further testified that “each case is different, but [complex percutaneous
2 retrieval] would be worth trying.” (Ex. F, “Hurst Dep. Tr.” at 101:8-
3 101:14). Lastly, Dr. Hurst’s expert report clearly states: “Because the
4 filter could not be removed using the standard techniques and
5 equipment recommended by Bard, Ms. Mulkey will have to undergo
6 one or more additional removal procedures. Due to the significant risks
7 and potential complications associated with open, surgical removal of
8 the Eclipse Filter, it is reasonable for the removal of the filter to first be
9 attempted via advanced, complex percutaneous techniques. If this
10 retrieval is unsuccessful, surgical removal will be necessary.” (Ex. B,
11 Hurst Report at pp. 12-13 ¶ (e)(i)(3)).

12 24. Plaintiff’s cardiothoracic surgeon expert, Dr. Derek Muehrcke, testified that
13 Ms. Mulkey’s Filter could “likely” be removed via a complex percutaneous procedure.
14 (Ex. G, July 24, 2017 Dr. Derek Muehrcke Deposition Transcript (“Muehrcke Dep. Tr.”),
15 at 154:22 to 155:14).

16 **RESPONSE: Controverted.** Dr. Muehrcke merely testified that it was
17 “more likely” that Ms. Mulkey’s IVC would be able to be removed than
18 Ms. Kruse, another plaintiff. (Ex. G, Muehrcke Dep. Tr. at 155:2-9).
19 Dr. Muehrcke did not say it was “likely” Ms. Mulkey’s filter can be
20 removed via complex percutaneous procedure. *Id.* In fact, Dr.
21 Muehrcke’s expert report indicates, “The Eclipse Filter implanted in
22 Ms. Mulkey exhibited the following failure modes: caudal migration,
23 tilt, fracture, perforation of the vena cava, penetration of adjacent
24 organs and structures, and irretrievability. Due to these failures, the
25 Eclipse Filter cannot be removed percutaneously . . .” (Ex. H, Muehrcke
26 Report at p. 1). The report goes on to say “[B]ecause of the
27 unsuccessful endovascular removal procedure, and based on the degree
28 of tilt and perforation, a complex open vascular surgery to remove the
filter is now the most reasonable option to prevent further problems
from [Ms. Mulkey’s] device.” (Ex. H, Muehrcke Report at p. 7).

25 25. Plaintiff’s expert, Dr. Muehrcke, acknowledges that all IVC filters are
26 known to have potential complications, including filter fracture, migration, tilt, and
27 perforation. (Ex. G, Muehrcke Dep. Tr. at 55:22 to 57:9).

28 **RESPONSE: Controverted.** Dr. Muehrcke testified that some filters
are much less likely to have the potential complication of tilt. (Ex. G,
Muehrcke Dep. Tr. at 56:12-16). Dr. Muehrcke also testified that the
Bard G2 filter had an unacceptable caudal migration risk that Bard
had been aware of since late 2005, early 2006, resulting in an

1 unacceptable safety profile for the G2 filter. (Ex. G, Muehrcke Dep. Tr.
2 at 57:10-20).

3 26. Dr. Hurst testified that Ms. Mulkey's filter perforated her IVC, caudally
4 migrated, and fractured. (Ex. F, Hurst Dep. Tr., at 74:23 to 75:16).

5 **RESPONSE: Uncontroverted with the clarification that these were not Ms.**
6 **Mulkey's only injuries that Dr. Hurst attributes to her Eclipse filter. For**
7 **example, Dr. Hurst's report also states that Ms. Mulkey's Eclipse filter**
8 **penetrated her adjacent organs and structures, as well as becoming**
9 **irretrievable. (Ex. B, Hurst Report at pp. 5-7, 12).**

10 27. Plaintiff testified that she never received a patient card or brochure
11 regarding her IVC filter. (Ex. E, Mulkey Dep. Tr. at 67:11-18).

12 **RESPONSE: Uncontroverted.**

13 28. Plaintiff testified that she never asked for any information about her filter
14 before it was implanted. (Ex. E, Mulkey Dep. Tr. at 67:16-18).

15 **RESPONSE: Controverted. Ms. Mulkey testified** [REDACTED]
16 **(Ex. D, Mulkey Dep. Tr. at 77:20-23; (Ex. C, Tompkins Dep. Tr. at 71:12-18).** [REDACTED]

17 [REDACTED] **(Ex. D, Mulkey Dep. Tr. at 79:3-7). Ms.**
18 **Mulkey** [REDACTED] **(Ex. D, Mulkey Dep. Tr. at**
19 **88:5-16).**

20 29. Plaintiff testified that she has never spoken to anyone at Bard. (Ex. E,
21 Mulkey Dep. Tr. at 167:11-13).

22 **RESPONSE: Uncontroverted but immaterial.**

23 30. Plaintiff testified that she has never visited Bard's website. (Ex. E,
24 Mulkey 28 Dep. Tr. at 69:24 to 70:1).

25 **RESPONSE: Uncontroverted but immaterial.**

26 31. Plaintiff testified that she did not know that Bard was the manufacturer of
27 her IVC filter until after she contacted her lawyer about her potential legal claim. (Ex. E,
28 Mulkey Dep. Tr. at 66:23 to 67:1).

RESPONSE: Uncontroverted but immaterial.

1 RESPECTFULLY SUBMITTED this 2nd day of October 2017.

2 GALLAGHER & KENNEDY, P.A.

3 By: /s/ Mark S. O'Connor
4 Mark S. O'Connor
5 2575 East Camelback Road
Phoenix, Arizona 85016-9225

6 LOPEZ McHUGH LLP
7 Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
8 100 Bayview Circle, Suite 5600
Newport Beach, California 92660

9 *Co-Lead/Liaison Counsel for Plaintiffs*

10 **CERTIFICATE OF SERVICE**

11 I hereby certify that on this 2nd day of October 2017, I electronically transmitted
12 the attached document to the Clerk's Office using the CM/ECF System for filing and
13 transmittal of a Notice of Electronic Filing.

14 /s/ Deborah Yanazzo
15
16
17
18
19
20
21
22
23
24
25
26
27
28